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08/442,277 05/16/95 BOYSE

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6287-026

EXAMINER

STANTON, B

ART UNIT

PAPER NUMBER

4

18M2/0914

PENNIE & EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711

1804

DATE MAILED:

09/14/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

*For Response Purposes Only*

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 30 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 10 AND 60-111 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 10 AND 60-111 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1804

Claims 10 and 60-111 are pending in the instant Application. Claims 1-9 and 11-59 were cancelled in the amendment filed 5/16/95 (Paper No. 3).

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claim 10, drawn to recombinant cells, classified in Class 435, subclass 240.2.
- II. Claims 60-62, 67-103 and 105-111, drawn to treatment methods wherein blood is directly administered, classified in Class 424, subclass 529.
- III. Claims 63-65, drawn to treatment methods wherein blood cells are grown *in vitro* prior to administration, classified in Class 435, subclass 240.21 and Class 424, subclass 529.
- IV. Claim 66 and 104, drawn to treatment methods wherein recombinant cells lines are prepared and used, classified in Class 514, subclass 44 and Class 424, subclass 529..

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the recombinant cells lines are useful for example in *in vitro* assays and differentiation studies which do not necessarily involve infusion into patients.

The inventions of Groups II-IV represent distinct therapeutic regimens. In the case of Group II, the invention involves direct utilization of unmodified blood. In the invention of Group III, the blood is grown *in vitro* prior to introduction into the patient. Such a method involves establishment of culture conditions, selection of particular cell types and regulation of the state of differentiation of constituent cells. None of the latter techniques are involved in the method of Group II. The method of Group IV requires the transfection of cells which involves selection of vectors, methods of introduction of nucleic acids into cells and selection methods. For these reasons the methods of groups II-IV represent materially different procedures which require non-coextensive considerations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, recognized divergent subject matter and further because the searches required for the different inventions are not coextensive, restriction for examination purposes as indicated is proper.

Art Unit: 1804

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Dr. Adriane Antler on 9/12/95 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton whose telephone number is (703) 308-2801. The examiner can normally be reached Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached at (703) 308-3153. The fax phone number for this Group is (703) 308-4312.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Brian R. Stanton, Ph.D.  
12 September 1995



**BRIAN R. STANTON**  
**PATENT EXAMINER**  
**GROUP 1800**